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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,839	06/23/2000	Markus Pompejus	BGI-127CP	9461

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EXAMINER
LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
1634	9

DATE MAILED: 05/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/602,839	POMPEJUS ET AL.	
	Examiner	Art Unit	
	Frank Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action* .

DETAILED ACTION

Location of Application

1. The Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1634.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4 and 9-16, drawn to an isolated nucleic acid molecule (1-4 and 9), classified in class 536, subclass 23.1; a vector (claims 10 and 11), classified in class 435, subclass 320.1; and host cells (claims 12-16), classified in class 435, subclass 252.3.

II. Claim 5, drawn to an isolated nucleic acid molecule which encodes a naturally occurring allelic variant, classified in class 536, subclass 23.1.

III. Claim 6, drawn to an isolated nucleic acid molecule comprising a nucleotide sequence which has at least 50% identity with the nucleotide sequence of claim 1, classified in class 536, subclass 23.1.

IV. Claim 7, drawn to an isolated nucleic acid molecule comprising a fragment of at least 15 nucleotides of the nucleotide sequence of claim 1, classified in class 536, subclass 23.1.

V. Claim 8, drawn to an isolated nucleic acid molecule which hybridizes to the nucleic acid molecule, classified in class 536, subclass 23.1.

VI. Claims 17 and 25-34, drawn to a method of producing a polypeptide (claim 17), classified in class 435, subclass 69.1; and a method for producing a fine chemical (claims 25-34), classified in class 435, subclass 3.

VII. Claims 18, 19, and 22, drawn to an isolated SES polypeptide, classified in class 530, subclass 350.

VIII. Claim 20, drawn to an isolated polypeptide, classified in class 530, subclass 350.

IX. Claim 21, drawn to an isolated polypeptide comprising a naturally occurring allelic variant of polypeptide, classified in class 530, subclass 350.

X. Claims 23 and 24, drawn to an isolated polypeptide, classified in class 530, subclass 350.

XI. Claim 35, drawn to a method for diagnosing the presence or activity of *Corynebacterium diphtheriae* in a subject, classified in class 436, subclass 94.

XII. Claim 36, drawn to a host cell , classified in class 435, subclass 320.1.

XIII. Claims 37 and 38, drawn to a host cell , classified in class 435, subclass 320.1.

3. The inventions are distinct, each from the other because of the following reasons:

4. Groups I, II, III, IV, V, XII, and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the

instant case, these inventions are directed to different products which have different modes of operation, different functions, or different effects because they are directed to different nucleotide sequences or host cells comprising different nucleic acid molecules.

Groups I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product such as the method in Group IX.

Groups I, VII, VIII, IX, and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these inventions are directed to different products which have different modes of operation, different functions, or different effects because nucleic acid (Group I) and protein (Groups VII to X) have different classifications (536/530).

Groups I and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product such as the method in Group VI.

Groups II, VI, and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these inventions are directed to a products (Group II) and two unrelated methods (Groups VI and XI) which have different modes of operation, different functions, or different effects because Groups VI and XI use nucleic acids in Group I, not nucleic acids in Group II.

Groups II, VII, VIII, IX, and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these inventions are directed to different products which have different modes of operation, different functions, or different effects because nucleic acid (Group II) and protein (Groups VII to X) have different classifications (536/530).

Groups III, VI, and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these inventions are directed to a products (Group III) and two unrelated methods (Groups VI and XI) which have different modes of operation, different functions, or different effects because Groups VI and XI use nucleic acids in Group I, not nucleic acids in Group III.

Groups III, VII, VIII, IX, and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case,

these inventions are directed to different products which have different modes of operation, different functions, or different effects because nucleic acid (Group III) and protein (Groups VII to X) have different classifications (536/530).

Groups IV, VI, and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these inventions are directed to a products (Group IV) and two unrelated methods (Groups VI and XI) which have different modes of operation, different functions, or different effects because Groups VI and XI use nucleic acids in Group I, not nucleic acids in Group IV (a nucleotide sequence with a length up to SEQ ID NO).

Groups IV, VII, VIII, IX, and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these inventions are directed to different products which have different modes of operation, different functions, or different effects because nucleic acid (Group IV) and protein (Groups VII to X) have different classifications (536/530).

Groups V, VI, and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these inventions are directed to a products (Group V) and two unrelated methods (Groups VI and XI)

which have different modes of operation, different functions, or different effects because Groups VI and XI use nucleic acids in Group I, not nucleic acids in Group V.

Groups V, VII, VIII, IX, and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these inventions are directed to different products which have different modes of operation, different functions, or different effects because nucleic acid (Group V) and protein (Groups VII to X) have different classifications (536/530).

Groups VI, VII, VIII, IX, and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these inventions are directed to a method (Group V) and four different unrelated product (Groups VII to X) which have different modes of operation, different functions, or different effects because Group VI uses nucleic acids in Group I, not polypeptides in Groups VII to X, to make a fine chemical.

Groups VI and XI are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group VI such as producing a polypeptide in claim 17 is not required for Group XI.

Groups VI, XII, and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,

different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these inventions are directed to a method (Group VI) and two different unrelated product (Groups XII and XIII) which have different modes of operation, different functions, or different effects because Group VI uses nucleic acids in Group I, not nucleic acids in Groups XII and XIII, to make a fine chemical.

Groups VII, VIII, IX, and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these inventions are directed to four different unrelated product (Groups VII to X) which have different modes of operation, different functions, or different effects because they are directed to different polypeptide sequences.

Groups VII, VIII, IX, X and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these inventions are directed to four different unrelated product (Groups VII to X) and a method (Group XI) which have different modes of operation, different functions, or different effects because Group XI uses nucleic acids in Group I, not polypeptide in Groups VII to X, for a diagnosing assay.

Groups VII, VIII, IX, X, XII, and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the

instant case, these inventions are directed to a different unrelated product which have different modes of operation, different functions, or different effects because Groups VII to X are polypepetides while Groups XII and XIII are host cells comprising nucleic acid molecules.

5. Sequence Election Requirement Applicable to Groups I, II, III, IV, VI, VIII, IX, X, XI, XII, and XIII.

The polynucleotide and polypeptide products in Groups I, II, III, IV, VI, VIII, IX, X, XI, XII, and XIII reads on patentably distinct SEQ ID Numbers. Each sequence is patentably distinct because the sequences are structurally unrelated sequences, and a further restriction is applied to each Group. Although the polynucleotides and polypeptides are related as the claimed polynucleotide is asserted to encode the claimed polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the nucleic acid may be used for processes other than the production of the protein as evidenced by the methods of at least group VI. Therefore, applicant must further elect a single SEQ ID NO. (See MPEP 803.04). Applicant is advised that examination will be restricted to only elected SEQ ID NO. and should not to be construed as a species election.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

Frank Lu
May 15, 2002